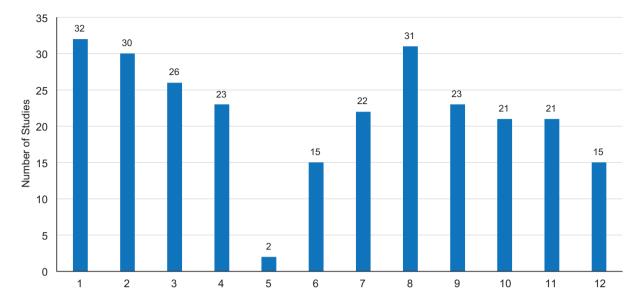
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Supplementary Fig. S3 Modified-Downs and Black score of abstracts from conference proceedings of RCTs and observational studies (33 studies): oncology¹⁻¹¹ and chronic inflammatory disease*10,12-32 studies.



* Aliaga et al, 10 reported data in patients with non-Hodgkin's lymphoma, chronic lymphocytic leukemia, rheumatoid arthritis, scleroderma, and dermatomyositis, thus was included in both oncology and chronic inflammatory diseases. RCT randomized control trial

- 1. Markus R, et al. Results of functional testing and pharmacokinetics comparing ABP 215 to bevacizumab. J Clin Oncol. 2015;33: Abstr: 711.
- 2. Filon O, et al. Efficacy and safety of BCD-021, bevacizumab biosimilar candidate, compared to Avastin: Results of international multicenter randomized double blind phase III study in patients with advanced non-squamous NSCLC. 2015 American Society of Clinical Oncology (ASCO) Annual Meeting; 29 May-2 June 2015;
- 3. Orlov SV, et al. Pharmacokinetics and safety of BCD-021, bevacizumab biosimilar candidate, compared to Amastin in patients. J Clin Oncol. 2014;32: Abstr:
- 4. Stenina MB, et al. Pharmacokinetics and safety of BCD-022, trastuzumab biosimilar candidate, compared to Herceptin in patients. J Clin Oncol. 2014;32(suppl): Abstr: e11576
- 5. Im Y, et al. Double-blind, randomized, parallel group, phase III study to demonstrate equivalent efficacy and comparable safety of CT-P6 and trastuzumab, both in combination with paclitaxel, in patients with metastatic breast cancer (MBC) as first-line treatment. J Clin Oncol. 2013;31:629.
- 6. Im Y, et al. Phase I/IIb clinical trial comparing PK and safety of trastuzumab and its biosimilar candidate CT-P6 [abstract S108]. 2013 (last update 2013). http://www.biosimilarz.com/wp-content/uploads/2013/03/ct-p06-in-mbc_abstract_st-gallen-2013_13mar2013.pdf. Accessed 22 June 2016>
- 7. Alexeev S, Zaritskey A, Volodicheva E, Loginov A, Orlova R, Dvornichenko V et al. Clinical comparability of BCD-020 to innovator rituximab in patients with indolent non-Hodgkin's lymphoma. Haematologica. 2014;99:144-5.
- 8. Kim S.J. et al. Safety, pharmacokinetic/pharmacodynamic profiles and efficacy of sait101, a biosimilar of rituximab in patients with diffuse large b-cell lymphoma. Haematologica. 2012;97 S317-S8.
- 9. Flores-Ortiz LF, et al. Physicochemical properties of rituximab. J Liq Chromatogr Relat Technol. 2014;37(10):1438-52.
- 10. Aliaga L, et al. Pharmacovigilance of anti CD 20 monoclonal antibody biosimilar at the Edgardo Rebagliati Martins Hospital-Peru. Drug Safety. 2013;36:925.
- 11. Mekhasian K, et al. Application of complementary HRMS methodologies for a thorough biosimilar comparability assessment. American Association of Pharmaceutical Scientists (AAPS) National Biotechnology Conference; 8-10 June 2015; San Francisco, CA
- 12. Yoo DH, et al. Impact of anti-drug antibody on efficacy and safety over week 24 in both CT-P10 and innovator rituximab treatment groups. Arthritis Rheum. 2014:65(suppl 10):S736.
- 13. Becker J-CP, et al. A Phase I trial comparing PF-05280586 (a potential biosimilar) and rituximab in subjects with active rheumatoid arthritis. Arthritis Rheum. 2014;66:S660-S1. 14. Barile-Fabris LA, et al. Incidence of adverse events in patients treated with intended copies of biologic therapeutic agents in Colombia and Mexico. Arthritis
- Rheum. 2014;66:S662-S. 15. Bandyopadhyay S. Safety and efficacy of rituximab-biosimilar for the treatment of moderate to severe rheumatoid arthritis patients following the failure of disease-modifying drugs: a case series from Apollo Gleneagles Hospital, Kolkata. Indian Rheumatology Association 29th Annual Conference (IRACON 2013); 6-8 December 2013: Kolkota, Calcutta, India
- 16. Kaur P, et al. A randomized, single-blind, single-dose, three-arm, parallel group study in healthy subjects to demonstrate pharmacokinetic equivalence of ABP 501 and adalimumab: Results of comparison with adalimumab (EU). Ann Rheum Dis. 2014;73:479
- 17. Shin D, et al. A Phase I pharmacokinetic study comparing SB5, an adalimumab biosimilar, and adalimumab reference product (Humira®) in healthy subjects. Ann Rheum Dis. 2015;74:459-60.
- 18. Kay J, et al. A phase 3, randomized, double-blind, active comparator study of the efficacy and safety of BOW015, a biosimilar infliximab,
- in patients with active rheumatoid arthritis on stable methotrexate doses. Ann Rheum Dis. 2014;73:64.

 19. Codreanu C, et al. Romanian Registry of Rheumatic Diseases: efficacy and safety of biologic therapy in rheumatoid arthritis. Ann Rheum Dis. 2015;74:458.
- 20. Gecse K, et al. Biosimilar Infliximab in inflammatory bowel diseases: first interim results from a prospective nationwide observational cohort. Zeitschrift für Gastroenterologie. 2015;53(05):A11.
- 21. Kierkus J. Preliminary assessment of efficacy and safety of switching between originator and biosimilar infliximab in paediatric Crohn disease patients. Gastroenterology. 2015;148(4 (Suppl 1)):S782-S3.
- 22. Molnar T, et al. Efficacy of the new infliximab biomarker CT-P13 induction therapy on mucosal healing in ulcerative colitis patients. J Crohns Colitis. 2015;9(Suppl 1):S382-S.
- 23. Murphy C, et al. Biosimilar but not the same. J Crohns Colitis. 2015;9(Suppl 1):S331-S2.
- 24. Yoo DH, et al. A randomized, double-blind, three-arm, parallel group, single-dose study to compare the pharmacokinetics, safety, and tolerability of three formulations of infliximab (CT-P13, EU-sourced infliximab and US-sourced infliximab) in healthy volunteers. Arthritis Rheum. 2014;66(suppl):1509
- 25. Udata C, et al. A Phase I pharmacokinetics trial comparing PF-06438179 (a potential biosimilar) and infliximab in healthy volunteers (REFLEXTIONS B537-01). Ann Rheum Dis. 2014;73:494.
- 26. Shin D, et al. A Phase I pharmacokinetic study comparing SB2, an infliximab biosimilar, and infliximab reference product (Remicade®)
- in healthy subjects. Ann Rheum Dis. 2015;74:703.

 27. Bae S-C, et al. A randomized, double-blind, Phase 3 equivalence trial comparing the etanercept biosimilar, HD203, with etanercept
- (Enbrel (R)), in combination with methotrexate (MTX) in patients with rheumatoid arthritis (RA). Arthritis Rheum. 2014;66:S1234-S 28. Chung H, et al. LBEC0101, An etanercept bisimilar, showed comparable rolerability and pharmacokinetic proles to those of etanercept in healthy male volunteers. Clin Pharmacol Ther. 2014;95:S39-S.
- 29. Lee YJ, et al. A Phase I pharmacokinetic study comparing SB4, an etanercept biosimilar, and etanercept reference product (Enbrel®) in healthy male subjects. Ann Rheum Dis. 2015;74:718.
- 30. Moctezuma JF, et al. Comparative, randomized, simple blind to evaluate efficacy and safety of infinitam® (etanercept), associated with methotrexate compared with Enbrel® (etanercept) associated with methotrexate in patients with modeate and severe rheumatoid arthritis.
- 31. An Y, et al. Treatment of rheumatoid arthritis with biological DMARDS in China: a multi-center cross-sectional study. Ann Rheum Dis. 2015;74:1302.
- 32. Santos-Moreno P, et al. Etanar A etanercept biosimilar is as effective as adalimumab and infliximab in a cohort of real-life of patients
- with rheumatoid arthritis. Ann Rheum Dis. 2015;74:789-90.